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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,910	01/31/2006	Jayachandra Suresh Babu	RLL-301US	2279

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EXAMINER	
BERCH, MARK L	

ART UNIT	PAPER NUMBER
1624	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,910	BABU ET AL.	
	Examiner	Art Unit	
	/Mark L. Berch/	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/31/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 13-23 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 74306 or EP 165164.

In both references, Example 1, step B, crystallizes the material from ethyl acetate. Step C shows the further conversion to Ganciclovir, Thus anticipating claim 23.

Claims 1-7, 13-23 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 532 878 (or 5792868).

See example 5. The crude product is dissolved in a mixture of chloroform and methanol. This solution was chromatographed, and 6.9 g of product were obtained. The solvent must have been removed for a weight to have been obtained. Example 6 shows conversion to Ganciclovir.

Claims 1-7, 13-23 are rejected under 35 U.S.C. 102(b) as being anticipated by 5583225.

See example 7; the factual situation is very similar.

Claims 1-7, 13-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Namavari.

Note page 158, first column, where the compound is called the triacetyl derivative of Ganciclovir, and was chromatographed using (CHCl3:CH3OH:H2O 5 92:7.2:0.8. Note that the product is called "pure". This is followed by conversion to Ganciclovir.

Claims 1-8, 13-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Field.

See preparation of IV on first paragraph of page 4141. There is an evaporation to a foam, which meets the claim language, and there is a further crystallization from dicholormethane. Claim 23 is covered in the next paragraph.

Claims 1-8, 13-23 are rejected under 35 U.S.C. 102(b) as being anticipated by PL157825 or Boryski (1999).

See translation of patent, of example 3. The Chloroform/methanol faction was evaporated, meeting to claim language, to give an oil. These were subsequently crystallized from ethanol. Boryski is similar; see example 3, both methods.

Claims 1-23 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 03/033498.

Examples 1-10 all cover the process of making the compound. In example 1 for example, There are actually three solvent removals. The first one gives a product which is less than 50% pure, just by solvent evaporation. Second is a separation in methanol, in which the undesired N-7 isomer is filtered off, leaving a methanol solution of the purified product. That solvent is evaporated, meeting the claim language. The further crystallization from toluene/methanol will also meet the claim language. Example 8 features a filtration of the chilled methanol solution, meeting the claim 10 limitation. The

subsequent addition and removal of Isopropanol meets the limitation of claims 11-12, as does the later methanol/toluene treatment. The distilling off of the isopropanol and also the methanol wash would provide drying, and drying is explicitly referred to in examples 9-10. Claim 23 is taught at page 7, lines 7-9.

The claims are not entitled to benefit of the foreign priority date of 10/31/2002. Additional material has been added for this case. For example, claim 1 covers inorganic solvents; the foreign priority paper does not. Claim 2 has "ketone" and claim 6 names three ketones; the foreign priority paper has only acetone. The numbers in claims 13-22 do not appear in the foreign priority paper. The "denatured spirit" of claim 5 is not in the foreign priority paper and there are other differences as well.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 532 878, Namavari, 5583225, Boryski.

Note above discussion. Although no method is giving for obtaining the product from the eluates of example 5, this is normally done by distilling off the solvent. At any rate, the claim 8 list covers essentially all conventional methods for solvent removal, and it is always

obvious to do something in a conventional manner. Claim 9 is itself a routine expedient, done normally as a matter of course. Likewise Namavari, 5583225, are similar

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17, and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 does not actually specify what is done to make the material more pure. All the claim requires is that the solvent be removed. The actual processes of the examples are much more complex. Every example involved the use of a protic solvent, every example involved heating, and every example involved cooling to below room temperature.

The term "pure form" is unclear. There is no way of knowing what is intended by that. Page 4, lines 15-19 has two levels of purity, each with three components. However, this is not presented in the form of a definition for the term, so one cannot be sure that this is intended. If it is, applicants need to decided whether they intend the standard of the first or second sentence, and insert that language into the claim. Note that this point covers even claims such as claim 13. That is, if one of the page 4 definitions is intended, claim 13

only specifies one of the three purity criteria, leaving it unclear what is required for the other two, the numbers of the first sentence, or the numbers of the second sentence.

Claim 11's "additional solvent" could have two meanings. It could be required to be the same as the original solvent, or it could be understood as not limited to that solvent, but also covering adding some other solvent. It is unclear which applicants intend.

The wording of claims 16-17 is unclear. The number could be understood as each impurity individually, or the sum of their amounts.

The "the solvent" of claim 12 is unclear. Is this the original solvent or the "additional solvent"

Claims 1-17, and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Such claim language cannot possibly be enabled. The claim as worded reads on dissolving an impure material in a solvent, and then evaporating the solvent, giving the original material (plus any possibly residual solvent). That will not give the material in pure form. More broadly, it covers recovery by any means from any solution, and applicants have not demonstrated that this can be accomplished. Further, assuming that the page 4 standard is what is meant by pure, not all methods succeeded, as the example 3 and processes, which both fall within the claims, did not come even close to those standards.

Claim Objections

Claims 1 and 23 are objected to because of the following informalities: Claims must end in period. Appropriate correction is required.

Specification

The abstract states that there is a process, but does not set forth what the process actually consists of.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Mark L. Berch/ whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark L. Berch/
Primary Examiner
Art Unit 1624

5/2/2008